

REGISTRATION PROCEDURE FOR VETERINARY MEDICINAL PRODUCTS WITH A CENTRALISED MARKETING AUTHORISATION (MA)

(applies also to veterinary medicinal products with a centralised MA already registered in EOF's database)

Marketing Authorisation Registration

For the registration of each veterinary medicinal product with a centralised MA in EOF's database, a request must be submitted at national level for the issuance of EOF codes for the approved pharmaceutical forms/strengths/pack sizes.

The Marketing Authorisation Holder (MAH) of veterinary medicinal products with a centralised MA is required to send an electronic dossier to protokollo@eof.gr, addressed to the Decision Issuing Department, including the following supporting documents:

1. Request for the issuance of codes
2. Relevant European Commission Decision, including its Annexes and approved pack sizes (corresponding Annex)
3. Completed form containing the details of the centralised MA of the veterinary medicinal product
4. Administrative fee of €50 (Euros) per pharmaceutical form/strength, payable to EOF's account at the Bank of Greece

Variation of Marketing Authorisation

The Marketing Authorisation Holder (MAH) of veterinary medicinal products with a centralised MA must notify EOF of every positive outcome regarding variations that affect the administrative data of the MA, by submitting the following to EOF:

1. Cover letter
2. Relevant European Commission Decision within two months of its issuance, or the EMA Opinion for any other case of variation
3. Completed form containing the details of the centralised MA of the veterinary medicinal product
4. Administrative fee of €50 (Euros) per pharmaceutical form/strength/pack size, in the event of issuing a code for a new pharmaceutical form, strength, or pack size, payable to EOF's account at the Bank of Greece
5. Administrative fee of €50 (Euros) in the case of variations concerning the local representative or the MAH (when no local representative is appointed), payable to EOF's account at the Bank of Greece
6. Administrative fee of €50 (Euros) in the case of a pack size deletion, payable to EOF's account at the Bank of Greece